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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,116	01/24/2002	Todd K. Whitehurst	AB-165U	1864

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EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,116	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,15-22,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,15-22,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-11 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (WO 98/37926) in view of Novak et al. (the article entitled: "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain").

Regarding claim 1, Schulman discloses providing at least one leadless stimulator (100) having at least two electrodes (112a and 112b); implanting the at least one stimulator adjacent to at least one nerve (see page 3, lines 9-14), at least in part responsible for sensations in a region experiencing pain (note page 6, lines 10-13); generating stimulation pulses in accordance with stimulation parameters (page 8, line 31- page 9, line 2); delivering the stimulation pulses to nerves adjacent to the at least one stimulator (see page 12, lines 5-9), wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve (see page 12, lines 2-5); and transmitting data from a transmitter of said stimulator to an external device (see page 10, lines 12-14).

Although Schulman et al. do not explicitly discuss a method for treating *chronic* pain, Schulman et al. teach that the device may be used to treat pain in general (see page 6, lines 10-16). It is further taught that a rechargeable battery may be employed in those applications requiring longer treatment times due to the recurring nature of the ailment (note for example page 8, lines 8-23 and page 20, line 20- page 21, line 6). Novak et al. further teach that chronic pain can be successfully treated with a peripheral nerve stimulator (see the last paragraphs on pages 1969 and 1971). Given the fact that one of the intended uses of the Schulman et al. device is to treat pain via nerve

stimulation, and given the teaching that the implant may be powered indefinitely from an external power source depending on the particular application at hand, with the treatment of chronic pain by peripheral nerve stimulators known, those of ordinary skill in the art presented with a patient experiencing chronic pain, would have seen the obviousness of utilizing the method of Schulman et al. to block chronic pain and provide a measure of relief to the patient.

Regarding the limitation concerning peripheral nerves, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation – especially in view of the teachings of Novak et al.. The type of pain to be treated and the physiology of the nervous system would naturally dictate where the most effective application site resides.

Regarding claims 2 and 3 and claims with similar limitations, note the pulse parameters listed in Table I (page 13).

Regarding claim 4 and claims directed to specific nerves or chronic pain locations, as reasoned above, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation. Comments applied in the rejection of similarly worded claim 1 apply here as well.

Regarding the step of identifying a patient experiencing sensations of chronic pain, it is axiomatic that Schulman et al. must identify a patient experiencing pain if they intend to use the device to treat pain as disclosed. Novak et al. further teach that successful pain relief depends upon accurate patient selection. Also note, comments made in the previous Office Action regarding claim 1 apply here as well since newly amended claim 4 has incorporated the subject matter of previous claim 1.

Regarding claim 8, all of the above comments made in support of the rejection of similarly worded limitations apply here as well.

Regarding claim 9 and claims directed to details of the sensor, note page 14, lines 9-28.

In regards to claim 10 and similarly worded claims, Schulman shows in Fig. 2 a diagram of the stimulator containing a sensor 188 coupled to the stimulation electrodes.

Regarding claim 15, comments paralleling those made in the rejection of claim 1 apply here as well.

Concerning claim 21, note page 14, lines 9-28.

Regarding claim 22, Schulman disclose that glucose –a blood borne substance— may be sensed (page 14, lines 9-28).

3. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (WO 98/37926) in view of Novak et al. (the article entitled: "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain") as applied to claims 1-11 and 15-22 above, and further in view of Nelson et al. (Pat. No. 6,480,745).

Schulman et al. and Novak et al. do not discuss the transmission of stimulation parameters to an external device (claim 27), with an interface for connection to a network so as to allow monitoring of the stimulator from a remote location (claim 28). Nelson et al., however, disclose a common and well-known method applicable to nerve stimulators that allows for such transmission and monitoring (note for example col. 2, lines 39-67, etc.). The performance of such a method has the explicit advantage of allowing continuous monitoring and immediate programming updates by remotely located medical personnel. Artisans of ordinary skill in the art desirous of such benefits would have therefore seen the obviousness of incorporating the steps of Nelson et al. into the method defined by Schulman et al. and Novak et al..

Response to Arguments

4. Applicant's arguments filed April 24, 2006 have been fully considered but they are not persuasive.

Regarding claim 1, the applicants argue that the newly added step of transmitting data from a transmitter of the stimulator to an external device is not taught or suggested in the prior art. It is unclear how the applicants have managed to come to this conclusion since the Schulman et al. reference clearly and explicitly discloses this old and well-known step (see the rejection of this limitation above).

Regarding claim 4, the applicants argue that Schulman and Novak do not teach or suggest a method of stimulating nerves that includes any of the nerves now recited. It is further argued that due to the unpredictable nature of biological systems and the possibility of side-affects, one of ordinary skill in the art would not know to stimulate at the claimed sites.

The examiner counters that Schulman et al. disclose a nerve stimulator that is substantially equivalent in size, shape and operation to the applicants' stimulator, and teach that such a stimulator may be used to decrease or relieve pain by placement proximate to the offending nerve. Novak et al. further teach that chronic nerve pain can be effectively treated via peripheral nerve stimulators, and discloses treatment applications to a variety of nerves including median and radial nerves –two nerves that the present applicants consider to be applicable to the invention (see for example the subject matter canceled from claim 4 by the applicants in the present response). Novak et al. further teach that pain relief with peripheral nerve stimulators can be successful, but that the success depends on accurate patient selection as determined by routine experimentation (see the Conclusion section and the general discussion on page 1971 of patient clinical trials). The possibility of unintended side-affects would not bar reasonably skilled artisans from the attempt (if the mere threat of initiating a side-affect prevented the attempt, medical research would likely grind to a halt since treatment induced side-affects are often common in the medical arts). The examiner considers the evidence of record to fully support a *prima facie* case of obviousness. Given the disclosures of Schulman et al. and Novak et al., one of ordinary skill in the art would reasonably expect the procedure to be successful on peripheral nerves in general, with mere routine experimentation required to determine the list of susceptible nerves and candidate patients. Related comments apply to claims 8 and 15.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KENNEDY SCHAETZLE
PRIMARY EXAMINER
7-8-06